

**REMARKS**

Claims 1-5, 7-10, 27, and 29-34 have been rejected under 35 U.S.C. §103(a) over “FAMILONI et al. (U.S. Pat. 5,690,691 hereinafter ‘CHEN’) in view of CIGAINA (U.S. Pat. 5,423,872).” However, in the discussion of this rejection, Chen (U.S. Pat. 5,690,691) is not mentioned or discussed. It appears that the rejection is based on Familoni (U.S. Pat. 6,327,503) in view of Cigaina (U.S. Pat. 5,423,872). The Applicant has assumed that this is, in fact, the rejection the Examiner intended to apply. Should this be incorrect, the Applicant respectfully requests clarification of the rejection and an opportunity to respond to the clarified rejection.<sup>1</sup>

Claims 6, 11-26 and 30 were also rejected under 35 U.S.C. §103(a) over “FAMILONI in view of CIGAINA (hereinafter ‘FAMILONI’) as applied to claims 1 and 7 above, and further in view of GORDON (U.S. Pat. 6,892,278).” This rejection is confusing in that it is not clear whether or not the term “FAMILONI” is intended to include only Familoni or Familoni in view of Cigaina since Cigaina is not mentioned in the discussion of the rejection and the column and page citations only refer to the Familoni. The Applicant has assumed that the term “FAMILONI” is to include both the Familoni and the Cigaina patents. In addition, the cited U.S. Patent No. 6,892,278 attributed by the Examiner to Gordon should be, we believe, U.S. Patent No. 6,895,278. For purposes of this response, the Applicant assumes the patent intended to be cited by the Examiner naming Gordon as the inventor is U.S. Patent No. 6,895,278. Should any of these assumptions be incorrect, the Applicant respectfully requests clarification of the rejection and an opportunity to respond to the clarified rejection.

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<sup>1</sup> Several attempts to contact the Examiner by telephone to clarify this and other rejections were unsuccessful.

Claim 28 has been rejected under 35 U.S.C. §103(a) as being unpatentable “over FAMILONI’ [sic] as applied to Claims 1 and 7 above, and further in view of GORDON or in view of GORDON and WERNICKE (U.S. Pat. 5,188,104).” Again, this rejection is confusing in that it is not clear whether or not the term “FAMILONI” is intended to include only Familoni or Familoni in view of Cigaina since Cigaina is not mentioned in the discussion of the rejection. Applicant has assumed that the term “FAMILONI” is to include both the Familoni and the Cigaina patents. Should this be incorrect, the Applicant respectfully requests clarification of the rejection and an opportunity to respond to the clarified rejection.

**I. The Rejections of Claims 1-5, 7-10, 27, and 29-34 are Traversed**

**A. Modifying Familoni According to Cigaina Would Destroy an Operating Principle of Familoni**

Claim 1 recites a system for gastric stimulation of a patient. The system includes a plurality of sensing electrodes that sense intrinsic gastric activity from a stomach wall of a patient. An implantable gastric stimulator is coupled to the plurality of sensing electrodes, receives the sensed intrinsic gastric activity, performs an analysis of the sensed intrinsic gastric activity, and determines whether to create an electrical stimulation based at least in part upon the analysis of the sensed intrinsic gastric activity. A plurality of stimulation electrodes conveys the electrical stimulation from the implantable gastric stimulator to the stomach wall of the patient. The electrical stimulation disrupts normal gastric activity of the stomach.

The Office Action stated that “Familoni also discloses a method for gastric stimulation comprising, sensing the intrinsic activity, determining the activity and when to apply the stimulation and then stimulating to disrupt gastric activity.” Furthermore, the Office Action stated that although Familoni did not teach stimulation of the stomach during

normal activity, that Cigaina taught the stimulation of the stomach during normal activity in order to slow up or speed up the stomach waves. Consequently, the Office Action asserted that it would have been obvious to modify the stimulation method of Familoni with a means to stimulate normal activity as taught by Cigaina “since such a modification would provide the stimulation method of Familoni with a means for providing a treatment method for obesity and/or eating disorders.” The Applicant respectfully disagrees with these assertions for the reasons stated below.

The Familoni patent is directed towards an implantable stimulator for sensing abnormal stomach activity. Once the abnormal activity is sensed, electrical stimulation is provided for a preset period of time to treat the abnormalities. More specifically, Familoni detects whether abnormalities – such as tachygastria are present—and then applies electrical stimulation to treat these abnormalities. Familoni, Abstract. For instance, the system senses the amplitude or period or slew rate of the electrogastrogram and then analyzes these parameters. Familoni, col. 6, lines 6-22. If the readings are abnormal, identification of the particular type of gastroarrhythmia is made. Familoni, Abstract. On the other hand, if the readings are normal, the device resets itself. See Familoni, FIG. 7. In other words, there is no disruption of any stomach activity—normal or otherwise. Put another way, Familoni treats abnormalities of the stomach and does not seek to cause abnormalities.

On the other hand, the Cigaina reference describes an implantable electrical stimulator that is used to alter the gastric motility across the entire stomach of the patient. The altering of the gastric motility of the patient is performed to prevent emptying of the stomach or to slow down gastric transit. In other words, Cigaina disrupts the normal activities of the stomach to cause abnormalities.

Consequently, to modify the Familoni reference according to Cigaina would destroy an operating principle of Familoni (i.e., it would change treating abnormalities to causing

abnormalities). If a proposed modification would change a principle of operation of a prior art reference, then the proposed modification is not, and cannot be, obvious. See MPEP 2143.01. For this reason, it is submitted that the proposed modification is non-obvious and claim 1 is allowable over the proposed combination.

Claim 29 is a method claim having recitations similar to claim 1. Consequently, it is submitted that claim 29 is allowable for the same reasons as claim 1. Claims 2-5, 7-10, 27, and 30-34 depend directly or indirectly upon claims 1 and 29. Since claims 1 and 29 are allowable, it is submitted that these remaining claims are also allowable.

**B. No Motivation to Combine the References Exists**

As mentioned, the Office Action stated that the Familoni and Cigaina reference could be combined because “such a modification would provide the stimulation method of Familoni with a means for providing a treatment method for obesity and/or eating disorders.”

However, the Familoni reference treats gastric abnormalities (e.g., gastric arrhythmia, bradygastria, dysrhythmia, tachygastria, or retrograde propagation or uncoupling). Familoni is silent as to treating a whole-body condition such as obesity.

Consequently, the Applicant submits that there is no motivation to combine the two references. More specifically, the treatment of specific gastric illnesses is different than treating a condition of the body such as obesity. Put another way, it is improper to scour the prior art to find the various claim elements and then combine the elements as claimed effectively using the Applicant’s own teachings as the motivation. See MPEP 2143.01.

Consequently, the Applicant submits that claim 1 is allowable over the proposed combination for this additional reason. As mentioned, claim 29 is a method claim having recitations similar to claim 1 and it is submitted that claim 29 is allowable for the same

reasons as claim 1. Claims 2-5, 7-10, 27, and 30-34 depend directly or indirectly upon claims 1 and 29. Since claims 1 and 29 are allowable, it is submitted that the remaining claims are also allowable.

## **II. The Rejections of Claims 6, 11-26 and 30 are Traversed**

Claims 6, 11-26 and 30 were rejected under 35 U.S.C. §103(a) over Familoni in view of Cigaina and in further view of Gordon. Claims 6 and 11-26 depend directly or indirectly upon claim 1 while claim 30 depends directly upon claim 29.

The proposed Familoni-Cigaina combination has been discussed above. Gordon describes a system for stimulating neuromuscular tissue in the stomach when a voltage across the tissue falls below a threshold. Gordon, col. 2, lines 35-47. In other words, the Gordon system is used to simulate normal stomach activity and is not used to cause abnormal activity. As such, it is submitted that the addition of Gordon does not correct the deficiencies with respect to the Familoni-Cigaina combination. Consequently, it is submitted that claims 6, 11-26, and 30 are allowable over the proposed combination for the same reasons as given above.

## **III. The Rejection of Claim 28 is Traversed**

Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Familoni in view of Cigaina in further view of Gordon and Wernicke. Claim 28 depends indirectly upon claim 1.

The proposed Familoni-Cigaina-Gordon combination has been discussed above. Wernicke describes a system of treating eating disorders by stimulating the stomach with electrical pulses. Wernicke col. 3, line 49- col. 4, line 4. The Wernicke system does not seek

to cause abnormal stomach behavior. As such, it is submitted that the addition of Wernicke does not correct the deficiencies with respect to the Familoni-Cigaina-Gordon combination. Consequently, it is submitted that the claim 28 is allowable over the proposed combination for the same reasons as given above.

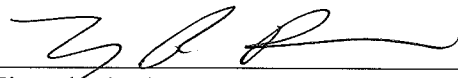
#### **IV. Conclusion**

Reconsideration and allowance of the application, as amended, are respectfully requested. In view of the foregoing, it is submitted that the application is in condition for allowance which is respectfully requested.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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